

1 Cabinet for Health and Family Services

2 Office of Health Policy

3 (New administrative regulation)

4 900 KAR 6:065. Certificate of need application process.

5 RELATES TO: KRS 216B.010-216B.130, 216B.330-216B.339, 216B.455, 216B.990

6 STATUTORY AUTHORITY: KRS 194A.030, 194A.050, 216B.040(2)(a)1, 216B.330

7 NECESSITY, FUNCTION, AND CONFORMITY: KRS 216B.040(2)(a)1 requires the

8 Cabinet for Health and Family Services to administer Kentucky's Certificate of Need

9 Program and to promulgate administrative regulations as necessary for the program.

10 This administrative regulation establishes the requirements necessary for the orderly

11 administration of the certificate of need application, review, decision, and

12 reconsideration process.

13 Section 1. Definitions. (1) "Cabinet" is defined by KRS 216B.015(5).

14 (2) "Certificate of Need Newsletter" means the monthly newsletter that is published  
15 by the cabinet regarding certificate of need matters and is available on the Certificate of  
16 Need Web site at <http://chfs.ky.gov/ohp/con>.

17 (3) "Days" means calendar days, unless otherwise specified.

18 (4) "Formal review" means the review of applications for certificate of need which  
19 are reviewed within ninety (90) days from the commencement of the review as provided  
20 by KRS 216B.062(1) and which are reviewed for compliance with the review criteria set  
21 forth at KRS 216B.040 and 900 KAR 6:070.

1 (5) "Nonsubstantive review" is defined by KRS 216B.015(17).

2 (6) "Owner" means a person as defined in KRS 216B.015(21) who is applying for  
3 the certificate of need and will become the licensee of the proposed health service or  
4 facility.

5 (7) "Proposed service area" means the geographic area the applicant proposes to  
6 serve.

7 (8) "Public information channels" means the Office of Communication and  
8 Administrative Review in the Cabinet for Health and Family Services.

9 (9) "Public notice" means notice given through:

10 (a) Public information channels; or

11 (b) The cabinet's Certificate of Need Newsletter.

12 (10) "Secretary" is defined by KRS 216B.015(25).

13 (11) "Show cause hearing" means a hearing during which it is determined whether a  
14 person or entity has violated provisions of KRS Chapter 216B.

15 Section 2. Letter of Intent. (1) OHP – Form 1, Certificate of Need Letter of Intent, as  
16 incorporated by reference in 900 KAR 6:055 shall be filed with the cabinet by all  
17 applicants for a certificate of need. This shall:

18 (a) Include those applicants requesting nonsubstantive review under the provisions  
19 of 900 KAR 6:075; and

20 (b) Not include those applicants requesting nonsubstantive review under the  
21 provisions of KRS 216B.095(3)(a) through (e).

22 (2) Upon receipt of a letter of intent, the cabinet shall within one (1) day provide the  
23 sender with written acknowledgment of receipt of the letter and shall publish notice of

1 the receipt in the next published certificate of need newsletter.

2 (3) An application for a certificate of need shall not be processed until the letter of  
3 intent has been on file with the cabinet for thirty (30) days.

4 Section 3. Certificate of Need Application. (1) An applicant for a certificate of need  
5 shall file an application with the cabinet on the appropriate certificate of need application  
6 form: OHP - Form 2A, OHP - Form 2B, or OHP - Form 2C as incorporated by reference  
7 in 900 KAR 6:055.

8 (2) When filing an application for certificate of need, the applicant shall file an  
9 original and one (1) copy of the appropriate certificate of need application form together  
10 with the prescribed fee set forth in 900 KAR 6:020 on or before the deadlines  
11 established by 900 KAR 6:060.

12 (3) Formal or nonsubstantive review of an application for a certificate of need shall  
13 not begin until the application has been deemed complete by the cabinet.

14 (4) The cabinet shall deem an application complete if the applicant has:

15 (a) Provided the cabinet with all of the information necessary to complete the  
16 application; or

17 (b) Declined to submit the requested information and has requested that its  
18 application be reviewed as submitted.

19 (5) Once an application has been deemed complete, the applicant shall not submit  
20 additional information regarding the application unless the information is introduced at a  
21 public hearing.

22 (6) Once an application has been deemed complete, it shall not be amended to:

23 (a) Increase the scope of the project;

- 1 (b) Increase the amount of the capital expenditure;
- 2 (c) Expand the size of the proposed service area;
- 3 (d) Change the location of the health facility or health service; or
- 4 (e) Change the owner, unless the application involves a licensed health facility and
- 5 a change of ownership with appropriate notice has occurred after the application was
- 6 submitted.

7 (7) An application that has been deemed complete may be amended at a public  
8 hearing to:

- 9 (a) Decrease the scope of the project;
- 10 (b) Decrease the amount of the capital expenditure; or
- 11 (c) Decrease the proposed service area.

12 (8) Applicants who have had proposals for certificates of need approved under the  
13 nonsubstantive review provisions of 900 KAR 6:075 or under the provisions of KRS  
14 216B.095(3)(a) through (e) may request that the cabinet change the specific location to  
15 be designated on the certificate of need if:

- 16 (a) The facility has not yet been licensed;
- 17 (b) The location is within the county listed on the certificate of need application; and
- 18 (c) The applicant files a written request with the cabinet within 180 days of the date  
19 of issuance of the certificate of need. A request shall include the reason why the change  
20 is necessary.

21 (9) If an application is not filed with the cabinet within one (1) year of the date of the  
22 filing of a letter of intent, the letter of intent shall expire, and the applicant shall file a new  
23 letter of intent at least thirty (30) days prior to submitting an application.

1 (10) If an application is withdrawn, the applicant shall file a new letter of intent at  
2 least thirty (30) days prior to resubmitting an application.

3 (11) An application that is not deemed complete within one (1) year from the date  
4 that it is filed shall expire and shall not be placed on public notice or reviewed for  
5 approval.

6 Section 4. Certificate of Need Review. (1) Prior to being reviewed for the approval or  
7 denial of a certificate of need, all applications for certificate of need shall be reviewed for  
8 completeness pursuant to Section 5 of this administrative regulation.

9 (2) Unless granted nonsubstantive review status under the criteria in 900 KAR  
10 7:075, an application for a certificate of need shall be reviewed for approval or denial  
11 according to the formal review criteria set forth in 900 KAR 6:070.

12 (3) If granted nonsubstantive review status under the criteria in 900 KAR 6:075, an  
13 application for a certificate of need shall be reviewed for approval or denial of the  
14 certificate of need according to the nonsubstantive review criteria set forth in 900 KAR  
15 6:075.

16 Section 5. Completeness Review. (1) Fifteen (15) days after the deadline for filing  
17 an application in the next appropriate batching cycle, the cabinet shall conduct an initial  
18 review to determine if the application is complete for formal review or nonsubstantive  
19 review requested pursuant to 900 KAR 6:075. Applications for which nonsubstantive  
20 review status has been requested pursuant to KRS 216B.095(3)(a) through (e) shall be  
21 reviewed within fifteen (15) days of receipt.

22 (2) If the cabinet finds that the application for formal review is complete, the cabinet  
23 shall:

1 (a) Notify the applicant in writing within one (1) day that the application has been  
2 deemed complete and that review of the application for the approval or denial of a  
3 certificate of need shall begin upon public notice being given; and

4 (b) Give public notice in the next appropriate certificate of need newsletter that  
5 review of the application for approval or denial of a certificate of need has begun.

6 (3) If the cabinet finds that the application for nonsubstantive review is complete, the  
7 cabinet shall notify the applicant in writing within ten (10) days that the application has  
8 been deemed complete and that review of the application for the approval or denial of a  
9 certificate of need shall begin upon public notice being given.

10 (4) A decision to grant or deny nonsubstantive review status shall be made within  
11 ten (10) days of the date the applicant is notified that the application has been deemed  
12 complete.

13 (5) The cabinet shall give public notice for applications granted nonsubstantive  
14 review status under 900 KAR 6:075 in the next appropriate certificate of need newsletter  
15 that status has been granted and that review of the application for approval or denial of  
16 a certificate of need has begun. Public notice for applications granted nonsubstantive  
17 review status according to KRS 216B.095(3)(a) through (e) shall be mailed to affected  
18 persons.

19 (6) A determination that an application is complete shall:

20 (a) Indicate that the applicant has responded to the necessary items on the  
21 application;

22 (b) Not be determinative of the accuracy of, or weight to be given to, the information  
23 contained in the application; and

1 (c) Not imply that the application has met the review criteria for approval of a  
2 certificate of need.

3 (7) If the cabinet finds that the application is incomplete, the cabinet shall:

4 (a) Provide the applicant with written notice of the information necessary to  
5 complete the application; and

6 (b) Notify the applicant that the cabinet shall not deem the application complete  
7 unless within fifteen (15) days of the date of the cabinet's request for additional  
8 information:

9 1. The applicant submits the information necessary to complete the application by  
10 the date specified in the request; or

11 2. The applicant requests in writing that the cabinet review its application as  
12 submitted.

13 (8) If, upon the receipt of the additional information requested, the cabinet finds that  
14 the application for formal review is complete, the cabinet shall:

15 (a) Notify the applicant in writing that:

16 1. The application for formal review has been deemed complete; and

17 2. Review of the application for the approval or denial of a certificate of need shall  
18 begin upon public notice being given; and

19 (b) Give public notice in the next appropriate certificate of need newsletter that  
20 review of the application for approval or denial of a certificate of need has begun.

21 (9) If, upon the receipt of the additional information requested, the cabinet finds that  
22 an application for nonsubstantive review is complete, the cabinet shall:

23 (a) Notify the applicant in writing that:

- 1        1. The application has been deemed complete;
- 2        2. Review of the application for the approval or denial of a certificate of need shall  
3 begin upon public notice being given; and
- 4        3. A decision to grant or deny nonsubstantive review status shall be made within ten  
5 (10) days of the date that the application was deemed complete; and
- 6        (b) Give public notice in the next appropriate certificate of need newsletter for  
7 applications granted nonsubstantive review status under 900 KAR 6:075 that status has  
8 been granted and that review of the application for approval or denial of a certificate of  
9 need has begun. Public notice for applications granted nonsubstantive review status  
10 according to KRS 216B.095(3)(a) through (e) shall be mailed to affected persons.
- 11        (10) If the application is incomplete, or if the information submitted is insufficient to  
12 complete the application, the cabinet shall:
- 13        (a) Request the information necessary to complete the application; and
- 14        (b) Inform the applicant that the application shall not be deemed complete and shall  
15 not be placed on public notice until:
- 16        1. The applicant submits the information necessary to complete the application; or  
17        2. The applicant requests in writing that its application be reviewed as submitted.
- 18        (11) Once an application has been deemed complete, an applicant shall not submit  
19 additional information to be made part of the public record unless:
- 20        (a) The information is introduced at a hearing; or
- 21        (b) In the case of a deferred application, the additional information is submitted at  
22 least twenty (20) days prior to the date that the deferred application is placed on public  
23 notice.

1 (12) A determination that an application is complete shall:

2 (a) Indicate that the application is sufficiently complete to be reviewed for approval or  
3 disapproval;

4 (b) Not be determinative of the accuracy of, or weight to be given to, the information  
5 contained in the application; and

6 (c) Not imply that the application has met the review criteria for approval.

7 Section 6. Notice of Decision. (1) The cabinet shall notify the applicant and any  
8 party to the proceeding of the final action on a certificate of need application within three  
9 (3) days.

10 (2) Notification of approval shall be in writing and shall include:

11 (a) Verification that the review criteria for approval have been met;

12 (b) Specification of any terms or conditions limiting a certificate of need approval,  
13 including limitations regarding certain services or patients. This specification shall be  
14 listed on the facility or service's certificate of need and license;

15 (c) Notice of appeal rights; and

16 (d) The amount of capital expenditure authorized, if applicable.

17 (3) Written notification of disapproval shall include:

18 (a) The reason for the disapproval; and

19 (b) Notice of appeal rights.

20 (4) An identical application for certificate of need that is disapproved shall not be  
21 refiled for a period of twelve (12) months from the original date of filing, absent a change  
22 in circumstances.

23 Section 7. Deferral of an Application. (1) An applicant may defer review of an

1 application by notifying the cabinet in writing of its intent to defer review.

2 (a) If the application has been granted nonsubstantive review status, the notice to  
3 defer shall be filed pursuant to 900 KAR 6:090 no later than five (5) days prior to the  
4 date that the decision is due on the application unless a hearing has been scheduled. If  
5 a hearing has been scheduled, the notice to defer shall be filed pursuant to 900 KAR  
6 6:090 no later than six (6) days prior to the date of the hearing.

7 (b) If the application is being reviewed under formal review, the notice to defer shall  
8 be filed pursuant to 900 KAR 6:090 no later than ten (10) days prior to the date that the  
9 decision is due on the application unless a hearing has been scheduled. If a hearing  
10 has been scheduled, the notice to defer shall be filed pursuant to 900 KAR 6:090 eight  
11 (8) days prior to the date of the hearing.

12 (c) If a hearing has been scheduled, the applicant shall also notify all parties to the  
13 proceedings in writing of the applicant's intent to defer the application.

14 (2) If deferral is requested, the application shall be deferred to the next regular  
15 batching cycle and shall be placed on public notice pursuant to the timetables set forth  
16 in 900 KAR 6:060.

17 (3) If an application is deferred, an applicant may update its application by providing  
18 additional information to the cabinet at least twenty (20) days prior to the date that the  
19 deferred application is placed on public notice.

20 (4) In order for a hearing to be held on a deferred application, a hearing shall be  
21 requested by either the applicant or an affected person within:

22 (a) Ten (10) days of the deferred application being placed on public notice if the  
23 application has been granted nonsubstantive review status; or

1 (b) Fifteen (15) days of the deferred application being placed on public notice if the  
2 application is being reviewed under the provision of formal review.

3 Section 8. Withdrawal of an Application. (1) An applicant may withdraw an  
4 application for certificate of need by notifying the cabinet in writing of the decision to  
5 withdraw the application prior to the entry of a decision to deny or approve the  
6 application.

7 (2) If a hearing has been scheduled or held on the application, the applicant shall  
8 also notify all parties to the proceedings in writing of the applicant's decision to withdraw  
9 the application.

10 Section 9. Location of New and Replacement Facilities. A certificate of need  
11 approved for the establishment of a new facility or the replacement of an existing facility  
12 shall be valid only for the location stated on the certificate.

13 Section 10. Requests for Reconsideration. (1) Requests for reconsideration shall be  
14 filed, pursuant to 900 KAR 6:090, within fifteen (15) days of the date of the notice of the  
15 cabinet's final decision relating to:

16 (a) Approval or disapproval of an application for a certificate of need;

17 (b) An advisory opinion entered after a public hearing;

18 (c) Revocation of a certificate of need; or

19 (d) A show cause hearing conducted in accordance with 900 KAR 6:090.

20 (2) A copy of the request for reconsideration shall be served by the requester on all  
21 parties to the proceedings.

22 (3) A party to the proceedings shall have seven (7) days from the date of service of  
23 the request for reconsideration to file a response to the request with the cabinet.

1 (4) If a hearing was held pursuant to subsection (1) (a), (b), or (c) of this section, the  
2 hearing officer that presided over the hearing shall enter a decision to grant or deny a  
3 request for reconsideration within thirty (30) days of the request being filed.

4 (5) If a hearing was held pursuant to subsection (1)(d) of this section, the secretary  
5 shall enter a decision to grant or deny a request for reconsideration within thirty (30)  
6 days of the request being filed.

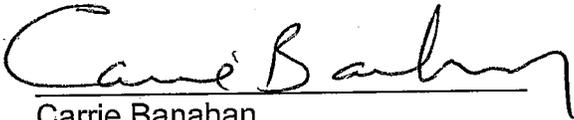
7 (6) If reconsideration is granted, the hearing shall be held by the cabinet in  
8 accordance with the applicable provisions of 900 KAR 6:090 Section 3 or Section 4  
9 within thirty (30) days of the date of the decision to grant reconsideration, and a final  
10 decision shall be entered by the cabinet no later than thirty (30) days following the  
11 conclusion of the hearing.

12 (7) If reconsideration is granted on the grounds that a public hearing was not held  
13 pursuant to KRS 216B.085, the applicant shall have the right to waive the  
14 reconsideration hearing if the deficiencies in the application can be adequately  
15 corrected by submission of written documentation.

900 KAR 6:065

This is to certify that the Executive Director of the Office of Health Policy has reviewed and recommended this administrative regulation prior to its adoption, as required by KRS 156.070(4)

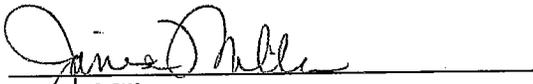
APPROVED:



Carrie Banahan  
Executive Director  
Office of Health Policy

4/29/09  
Date

APPROVED:



Janie Miller  
Secretary  
Cabinet for Health and Family Services

5/15/09  
Date

900 KAR 6: 065

A public hearing on this administrative regulation shall, if requested, be held on July 21, 2009, at 9:00 a.m. in the Public Health Auditorium located on the First Floor, 275 East Main Street, Frankfort, Kentucky 40621. Individuals interested in attending this hearing shall notify this agency in writing by July 14, 2009, five (5) workdays prior to the hearing, of their intent to attend. If no notification of intent to attend the hearing is received by that date, the hearing may be canceled. The hearing is open to the public. Any person who attends will be given an opportunity to comment on the proposed administrative regulation. A transcript of the public hearing will not be made unless a written request for a transcript is made. If you do not wish to attend the public hearing, you may submit written comments on the proposed administrative regulation. You may submit written comments regarding this proposed administrative regulation until close of business July 31, 2009. Send written notification of intent to attend the public hearing or written comments on the proposed administrative regulation to:

**CONTACT PERSON:** Jill Brown, Office of Legal Services, 275 East Main Street 5 W-B, Frankfort, KY 40621, (502) 564-7905, Fax: (502) 564-7573

## REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Regulation: 900 KAR 6:065

Contact Person: Carrie Banahan or Shane O'Donley, 564-9592

(1) Provide a brief summary of:

(a) What this administrative regulation does: This administrative regulation establishes the policies for submitting a letter of intent to submit a certificate of need application, submitting certificate of need applications, review of applications, deferral or withdrawal of applications, location of new and replacement facilities, notice of decisions by the cabinet, and requests for reconsider of decisions for the certificate of need program. Formerly 900 KAR 6:050 established the requirements necessary for the orderly administration of the certificate of need program. Due to the large size of that administrative regulation, LRC staff requested that it be separated into several smaller regulations. Therefore, this new administrative regulation was drafted to include the policies for submitting a letter of intent to submit a certificate of need application, submitting certificate of need applications, review of applications, deferral or withdrawal of applications, location of new and replacement facilities, notice of decisions by the cabinet, and requests for reconsider of decisions for the certificate of need program. This regulation creates no substantive change to current policies.

(b) The necessity of this administrative regulation: This administrative regulation is necessary to comply with the content of the authorizing statute, KRS 216B.010-216B.130, 216B.330-216B.339, 216B.455, 216B.990.

(c) How this administrative regulation conforms to the content of the authorizing statutes: This administrative regulation conforms to the content of KRS 216B.010-216B.130, 216B.330-216B.339, 216B.455, 216B.990 by establishing the policies for submitting a letter of intent to submit a certificate of need application, submitting certificate of need applications, review of applications, deferral or withdrawal of applications, location of new and replacement facilities, notice of decisions by the cabinet, and requests for reconsider of decisions for the certificate of need program.

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: This administrative regulation assists in the effective administration of KRS 216B.010-216B.130, 216B.330-216B.339, 216B.455, 216B.990 by establishing the policies for submitting a letter of intent to submit a certificate of need application, submitting certificate of need applications, review of applications, deferral or withdrawal of applications, location of new and replacement facilities, notice of decisions by the cabinet, and requests for reconsider of decisions for the certificate of need program.

(2) If this is an amendment to an existing administrative regulation, provide a brief summary of:

(a) How the amendment will change this existing administrative regulation: This is a new administrative regulation.

(b) The necessity of the amendment to this administrative regulation: This is a new administrative regulation.

(c) How the amendment conforms to the content of the authorizing statutes: This is a new administrative regulation.

(d) How the amendment will assist in the effective administration of the statutes: This is a new administrative regulation.

(3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation: This administrative regulation affects an entity wishing to file an application for the certificate of need program. Approximately 100 entities file a certificate of need application each year.

(4) Provide an analysis of how the entities identified in question (3) will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including:

(a) List the actions that each of the regulated entities identified in question (3) will have to take to comply with this administrative regulation or amendment: As the policies for submitting a letter of intent to submit a certificate of need application, submitting certificate of need applications, review of applications, deferral or withdrawal of applications, location of new and replacement facilities, notice of decisions by the cabinet, and requests for reconsider of decisions for the certificate of need program are currently established and operational, no new action will be required of regulated entities to comply with this regulation.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3): As the policies for submitting a letter of intent to submit a certificate of need application, submitting certificate of need applications, review of applications, deferral or withdrawal of applications, location of new and replacement facilities, notice of decisions by the cabinet, and requests for reconsider of decisions for the certificate of need program set forth in the administrative regulation are currently established and operational, no cost will be incurred by regulated entities to comply with this regulation.

(c) As a result of compliance, what benefits will accrue to the entities identified in question (3) This administrative regulation will provide potential health care providers with a mechanism to establish health care facilities and services in compliance with KRS 216B.

(5) Provide an estimate of how much it will cost the administrative body to implement this administrative regulation:

(a) Initially: No additional costs will be incurred to implement this administrative regulation as entities already adhere to the policies for issuance of advisory opinions for the certificate of need program.

(b) On a continuing basis: No additional costs will be incurred to implement this administrative regulation on a continuing basis.

(6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation: The source of funding to be used for the implementation and enforcement of this administrative regulation will be from Office of Health Policy's existing budget. As stated above, the policies for submitting a letter of

intent to submit a certificate of need application, submitting certificate of need applications, review of applications, deferral or withdrawal of applications, location of new and replacement facilities, notice of decisions by the cabinet, and requests for reconsider of decisions for the certificate of need program are already used as part of our normal operations so no additional funding will be required.

(7) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new or by the change if it is an amendment: No increase in fees or funding will be necessary to implement this administrative regulation.

(8) State whether or not this administrative regulation established any fees or directly or indirectly increased any fees: This administrative regulation does not establish or increase any fees.

(9) TIERING: Is tiering applied? (explain why or why not) Tiering is not applicable as compliance with this administrative regulation applies equally to all individuals or entities regulated by it.

FISCAL NOTE ON STATE OR LOCAL GOVERNMENT

Regulation No. 900 KAR 6:065

Contact Person: Carrie Banahan or  
Shane O'Donley

1. Does this administrative regulation relate to any program, service, or requirements of a state or local government (including cities, counties, fire departments, or school districts)?

Yes  X  No

If yes, complete questions 2-4.

2. What units, parts or divisions of state or local government (including cities, counties, fire departments, or school districts) will be impacted by this administrative regulation? This administrative regulation affects the Office of Health Policy within the Cabinet for Health and Family Services.

3. Identify each state or federal statute or federal regulation that requires or authorizes the action taken by the administrative regulation. KRS 216B.010-216B.130, 216B.330-216B.339, 216B.455, 216B.990.

4. Estimate the effect of this administrative regulation on the expenditures and revenues of a state or local government agency (including cities, counties, fire departments, or school districts) for the first full year the administrative regulation is to be in effect.

(a) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for the first year? This administrative regulation will not generate any revenue.

(b) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for subsequent years? This administrative regulation will not generate any revenue.

(c) How much will it cost to administer this program for the first year? No additional costs will be incurred to implement this administrative regulation.

(d) How much will it cost to administer this program for subsequent years? No additional costs will be incurred to implement this administrative regulation on a continuing basis.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Revenues (+/-):      Expenditures (+/-):      Other Explanation: